AO 440 (Rev. 10/93) Summons in a Civil Action

United States District Court

Northern DISTRICT OF California

AVIGEN, INC., a Delaware corporation,

E-filing

SUMMONS IN A CIVIL ACTION

V.

CASE NUMBER:

RESEARCH CORPORATION TECHNOLOGIES, INC., a Delaware corporation,

PVT

C02 0880

TO: (Name and address of defendant)
Research Corporation Technologies, Inc.
101 North Wilmot Road, Suite 600
Tucson, Arizona 85711-3365

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Cooley Godward LLP
William G. Gaede, III
Brian E. Mitchell
One Maritime Plaza, 20th Floor
San Francisco, CA 94111
Phone: 415.693.2000
FAX: 415.951.3699

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

RICHARD W. WIEKING

ERK

FEB 21 2002

DATE

HELEN L. ALMACEN

(BY) DEPUTY CLERK

AO-440

AO 440 (Rev. 10/93) Summons in a Civil Action

RETURN OF SERVICE

Service of the Summons and Complaint was made by me [1]	DATE
NAME OF SERVER (PRINT)	TITLE

Check one box below to indicate appropriate method of service

☐ Served personally upon the defendant. Place where served: _____

☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were left: _____

☐ Returned unexecuted: _____

☐ Other *(specify)*: _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United Stated of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____
Date

_____
Signature of Server

_____
Address of Server

1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
WILLIAM G. GAEDE III (136184)
BRIAN E. MITCHELL (190095)
One Maritime Plaza, 20th Floor
San Francisco, CA 94111-3580
Telephone: (415) 693-2000
Facsimile: (415) 951-3699

Attorneys for Plaintiff
AVIGEN, INC.

E-filing

PVT

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

C02 0880

AVIGEN, INC., a Delaware corporation,

Plaintiff,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC., a Delaware corporation,

Defendant.

No.

COMPLAINT FOR (1) BREACH OF CONTRACT; (2) BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

Demand For Jury Trial

COMPLAINT

For its complaint against the defendant, Research Corporation Technologies, Inc. ("RCT"), the plaintiff, Avigen, Inc. ("Avigen"), alleges and states as follows:

PARTIES AND JURISDICTION

1. Avigen is a Delaware corporation having its principal place of business in Alameda, California.

2. Avigen is informed and believes, and on such information and belief alleges, that RCT is a Delaware corporation having its principal place of business in Tucson, Arizona.

3. Avigen's claims of breach of contract and breach of the implied covenant of good faith and fair dealing are based on the allegation that RCT has intentionally and unreasonably violated its duty of candor before the Patent and Trademark Office (the "PTO") and engaged in

acts of inequitable conduct. Avigen alleges that this destroyed the value of the exclusive patent license granted to Avigen pursuant to the parties' contract by rendering that patent's claims unenforceable.

4. Determining the merits of this allegation will necessarily require the resolution of substantial questions of federal patent law including, but not limited to, resolving issues arising under 35 U.S.C. Sections 1 and 112, 37 C.F.R. § 1.56, MPEP § 2001, the PTO's policies and procedures, the surrounding body of interpretative case law addressing inequitable conduct as established by the Federal Circuit, and the federal district court decisions applying that body of law. Correspondingly, this action arises under the patent laws of the United States, and this Court has jurisdiction pursuant to 28 U.S.C. § 1338. *See Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1331 (Fed. Cir. 1998) and *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000).

5. Avigen is informed and believes, and on such information and belief alleges, that RCT is subject to personal jurisdiction in this district.

6. Venue is proper in this district under 28 U.S.C. § 1391.

BACKGROUND

A. The License Agreement.

7. On or about May 15, 1992, a patent license agreement (the "License Agreement") was executed between RCT (Licensor), and Vestmark, Inc. (Licensee). Vestmark subsequently merged with Avigen. Avigen became Vestmark's successor-in-interest to the License Agreement, and Avigen assumed the role of Licensee under the terms of the parties' agreement and subsequent amendments to that agreement. A copy of this License Agreement, its exhibits, and its amendments, is attached to this complaint as Exhibit A and the contents of this License Agreement are incorporated herein by reference.

8. RCT licensed to Avigen exclusive rights to an invention directed towards gene therapy that was allegedly created by Dr. Arun Srivastava. These rights included an exclusive license under all patents that would issue from Patent Application No. 07/789,917 (the '917 application), which had been filed by Dr. Srivastava and was assigned to RCT.

9. Avigen bargained for, and obtained, RCT's promise to maintain and prosecute pending patent applications relating to the invention and to exercise "its reasonable efforts to obtain patent protection on the invention...." In addition, Avigen obtained the right to sublicense the patents that would issue from such patent applications.

10. Avigen provided RCT with substantial consideration pursuant to this License Agreement in exchange for these rights, including the payment of royalties and the transfer of Avigen stock.

B. RCT's Duty of Candor.

11. Applicants for patents have a general duty of candor and good faith in their dealings with the PTO and have an affirmative obligation to disclose to the PTO all information they know to be material to the examination of a pending application pursuant to 37 C.F.R. § 1.56. This duty extends to applicants and their representatives, such as their attorneys, and to all others associated with the patent's prosecution, including every person who is substantively involved in the preparation or prosecution of the application. This duty runs until the time the patent issues.

12. Thus, the representatives of RCT (as assignee of the '917 application), those associated with the prosecution, and the inventor, were all under a duty to disclose material information to the PTO during the application's prosecution.

13. Notwithstanding these obligations, Avigen is informed and believes, and on such information and belief alleges, that these RCT representatives, those associated with the prosecution, and the inventor, failed to disclose certain material references to the PTO and described and claimed certain embodiments of an invention that they knew were neither enabled nor operable.

C. RCT's Breach of Its Duty of Candor and Acts of Inequitable Conduct.

14. The '917 application was filed on November 8, 1991. This application described an invention directed to a specific "vector" (*i.e.*, a DNA delivery agent) that is used for gene therapy. This vector is derived from a natural virus called adeno-associated virus. Specifically, the vector consists of two inverted terminal repeats (ITRs) of adeno-associated virus (AAV) that flank a "gene" and a "promoter." A gene is a piece of DNA that codes for a protein and a promoter is a

piece of DNA that dictates how much and in what cell types the gene is "expressed" (*i.e.*, is translated to make the corresponding protein).

15. The promoter described and claimed in the '917 application must direct "cell-specific expression" of the gene. That is, the promoter must direct the expression of the gene only in certain cell types (*e.g.*, the gene is expressed in liver cells, but not muscle cells). The promoter exemplified in the '917 application is the B19p6 promoter, which was described in the '917 application as effecting gene expression specifically (that is, exclusively) in erythroid or erythroid progenitor cells.

16. In addition, the '917 application described and claimed an invention limited to expression vectors and virions (*i.e.*, a vector packaged in a viral coat) "for site-specific integration." That is, the gene is incorporated into the host DNA at a particular site or sites. Specifically, the '917 application discloses the site of integration as being on chromosome 19.

17. On November 25, 1992, during the prosecution of the '917 application, a second application on the invention was filed by Dr. Srivastava and RCT as a continuation-in-part of the '917 application. This second application, Application No. 07/982,193, issued as U.S. Patent No. 6,261,834 (the '834 patent) on July 17, 2001. This patent lists Dr. Srivastava as the sole inventor and was assigned to RCT. The '834 patent is exclusively licensed to Avigen pursuant to the License Agreement.

18. Except for limited new matter that was added in 1992, the '834 patent relies on the '917 application's disclosure and claims a "site-specific" vector that provides "cell-specific gene expression," as well as host cells that are transfected with that vector. The '834 patent also claims virions for site-specific integration that provide for cell specific expression. As in the '917 application, the only promoter used to support the claims of the '834 patent was the B19p6 promoter and the site of integration was described as being on chromosome 19.

19. However, prior to the '834 patent's issuance, RCT knew, as described more fully below, that the B19p6 promoter was not cell specific. This promoter is, in fact, highly active in non-erythroid cells following transfection with a vector and infection with a virion. Indeed, several researchers, including the inventor Dr. Srivastava, had concluded prior to the issuance of

the '834 patent that the B19p6 promoter is not cell-specific.

20. Thus, for example, Liu, *et al.* published a peer-reviewed manuscript in 1991 wherein the authors determined that the B19p6 promoter is not cell specific following the transfection of nonpermissive cells (*i.e.*, nonerythroid or erythroid progenitor cells) with a vector containing the B19p6 promoter. (Journal article by Liu, *et al.*, titled "*Indiscriminate Activity from the B19 Parvovirus P6 Promoter in Nonpermissive Cells*," Virology, 182:361-364 (1991).) This conclusion was based on data summarized in Figure 2 of the paper, and the authors note that the B19p6 promoter was equally active in HeLa (epithelial), K562 (erythroleukemia), Raji (B lymphoid), Jurkat, and CEM (T lymphoid) cells, and did not display any cell specificity.

21. In 1995, Dr. Srivastava and others published a peer-reviewed manuscript acknowledging that the B19p6 promoter is not cell specific, finding that "[n]onerythroid human cells, such as HeLa and KB, allow expression from the B19p6 promoter . . . following . . . transfection . . . ." in the context of an AAV-derived vector. (Journal article by Ponnazhagan, *et al.*, titled "*Transcriptional Transactivation of Parvovirus B19 Promoters in Nonpermissive Human Cells by Adenovirus Type 2*," Journal of Virology, Dec. 1995, pp. 8096-8101.) The authors state that "abundant expression from this [B19p6] promoter has been documented by us and others following . . . transfection" in HeLa, KB, and K562 cells. The same manuscript also shows that a significant level of B19p6 promoter activity was observed when nonpermissive 293 cells were infected with virions. In addition, this article cites the Liu, *et al.* article referenced above, thus establishing that Dr. Srivastava was aware of the Liu, *et al.* article and its conclusions regarding the B19p6 promoter's lack of cell specificity by at least 1995, if not before.

22. In 1996, Dr. Srivastava and others published another peer-reviewed manuscript in which they again conclude that the B19p6 promoter is not cell specific following transfection of vectors into host cells. (Journal article by Ponnazhagan, *et al.*, titled "*Differential Expression in Human Cells from the p6 Promoter of Human Parvovirus B19 Following Plasmid Transfection and Recombinant Adeno-Associated Virus 2 (AAV) Infection: Human Megakaryocytic Leukaemia Cells Are Non-Permissive for AAV Infection*," Journal of General Virology, 77:1111-1122 (1996).) Moreover, the authors discuss the Liu, *et al.* article in some detail, repeating the same type of

experiment that is described in that article, and obtaining the same results, *i.e.*, a determination that the B19p6 promoter is not cell specific following transfection.

23. And in 1998, in an article published by Gareus, *et al.*, again researchers documented that the B19p6 promoter was not cell specific, finding that "[a]fter transfection into HeLa, CEM, BJAB, and K562 cells, the p6 promoter was found to be highly active." (Journal article by Gareus, *et al.*, titled "*Characterization of cis-Acting and NS1 Protein-Responsive Elements in the p6 Promoter of Parvovirus B19*," Journal of Virology, Jan. 1998, pp. 609-616.) As illustrated in Figure 5 of this article, the B19p6 promoter did not display cell specificity in any of the cell lines tested thus establishing that the B19p6 promoter is not cell specific following transfection.

24. In addition, Dr. Srivastava had also concluded prior to the issuance of the '834 patent that the expression vectors and virions described and claimed in that patent did not provide "site-specific integration." In fact, Dr. Srivastava and others published a peer-reviewed manuscript in 1995 that acknowledged this lack of site-specificity. (Journal article by Ponnazhagan, *et al.*, titled "*Lack of Site-Specific Integration of the Recombinant Adeno-Associated Virus 2 Genomes in Human Cells*," Human Gene Therapy, Feb. 1997, pp. 275-284.) Specifically, the authors state that "our data are consistent with previous studies documenting the lack of site-specific integration of the recombinant AAV genomes into human chromosome 19."

25. These publications were highly material to the patentability of the invention claimed in Dr. Srivastava's patent. Claim 1 of the '834 patent, for example, covers a "vector for site-specific integration and cell-specific gene expression comprising two inverted terminal repeats of adeno-associated virus 2 and at least one cassette comprising a promoter capable of effecting cell-specific expression." And, by way of another example, claim 11 of the '834 patent allegedly covers all host cells transfected by the described vector that include a promoter capable of cell specific expression. But the references described above establish that the only promoter identified in the '834 patent – the B19p6 promoter – is not capable of cell-specific expression following transfection of the host cell with a vector or infection of a host cell with a virion. These references should have been brought to the PTO examiner's attention under the duty of candor, for example,

so as to allow the examiner to substantiate any doubts that the asserted scope of objective enablement was in fact commensurate with the scope of protection sought.

26. Moreover, the manuscripts published by the inventor and others directly contradict the argued novelty and nonobviousness of the claimed invention. For example, the cell specificity provided by the B19p6 promoter was raised and discussed throughout the '834 patent's prosecution history. In fact, RCT even appealed an issue relating to cell specificity following a 35 U.S.C. § 103 rejection over certain references. The decision on appeal reversing this rejection specifically mentioned the cell specificity of the promoter as an important aspect of the claimed invention.

27. Avigen is informed and believes, and on such information and belief alleges, that Dr. Srivastava was, at all times relevant herein, acting as the agent and/or employee of RCT with respect to the prosecution of the '834 patent before the PTO. Correspondingly, Avigen alleges that RCT knew about these publications well before the patent's issuance by way of Dr. Srivastava because all but one reference (Gareus) was either authored by the named inventor or cited in the inventor's own publications.

28. In addition, prior to the issuance of the '834 patent, all but one of the references (the inventor's 1996 article) were either provided directly to RCT by Avigen or the conclusions contained therein were brought to RCT's attention as material information that should be disclosed to the PTO under the duty of candor. And Avigen is informed and believes, and on such information and belief alleges, that RCT was aware of the inventor's 1996 article because this article is cited (as "submitted for publication") in the inventor's 1995 article, which was provided to RCT by Avigen.

29. Thus, for example, during a March 15, 2001 meeting between Avigen representatives (Dr. John Monahan, President & CEO and Dr. Kenneth G. Chahine, Vice President and Chief Patent Counsel) and RCT representatives (Timothy J. Reckart, Sr. Vice President & General Counsel and Dr. Bennett Cohen, Director, Commercialization), Avigen and RCT discussed the existence and importance of these references. Dr. Chahine, a Registered Patent Attorney (Reg. # 42398), informed Mr. Reckart, a Registered Patent Attorney (Reg. # 33274), that

the overwhelming body of scientific evidence led to the conclusion that the B19p6 promoter is not cell specific, that the invention does not integrate site-specifically, and that this was material information that had not been disclosed to the PTO.

30. This discussion was memorialized in a letter, and an accompanying memorandum that attached copies of three of these references (identified above in ¶¶ 20, 21, and 23), which was dated May 9, 2001 and sent by Federal Express to Mr. Reckart by Dr. Monahan on or about May 22, 2001. This letter was the subject of a conference call between Avigen and RCT representatives (Dr. Monahan, Dr. Chahine, Mr. Reckart, and Dr. Cohen) on June 25, 2001. And Dr. Chahine also raised these issues with RCT representatives, including Dr. Cohen and Mr. Gary Munsinger, well in advance of the March 15 meeting and confirming letter, starting as early as about April 1, 1999.

31. As evidenced by the patent's prosecution history, at no point during the '834 patent's prosecution did RCT disclose the information that is described above. Avigen is informed and believes, and on such information and belief alleges, that RCT's representatives knew this information was material to the patentability of the claimed invention, as evidenced by the inventor's own publications and the fact that Avigen brought the materiality of this information to the attention of RCT's patent attorney prior to the '834 patent's issuance.

32. RCT's failure to disclose each of these references to the PTO was, at a minimum, in violation of the general duty of candor described by MPEP § 2001 and required by 37 C.F.R. § 1.56, as well as in violation of the general obligation to disclose fully all information that a reasonable examiner would consider important to the patentability of the invention that is claimed.

33. Avigen is informed and believes, and on such information and belief alleges, that one or more of RCT's representatives, including Dr. Srivastava, intentionally concealed these references (and the conclusions as to cell specificity and site-specific integration as described therein), and by reason thereof, the '834 patent's claims were rendered unenforceable based on this conduct.

D. RCT has Denied Avigen the Benefit of Its Bargain.

34. RCT's intentional conduct rendered the licensed patent unenforceable as a matter of

law. As such, Avigen has been denied the benefit of valuable intellectual property rights that it sought to obtain pursuant to the parties' license agreement.

35. This conduct has destroyed or, at a minimum, irreparably harmed Avigen's ability to sublicense the '834 patent.

36. Moreover, RCT's actions have rendered the exclusivity of Avigen's license under the '834 patent essentially worthless. With an exclusive patent license comes the right to exclude competitors from practicing the patented technology. But, due to RCT's actions, Avigen is now denied the ability to assert its exclusive rights in good faith to deter its competition.

CLAIMS FOR RELIEF

First Claim for Relief (Breach of Contract)

37. Avigen incorporates the allegations and averments of paragraphs 1 through 36 as fully set forth in this claim for relief.

38. A written contract existed between the parties.

39. Avigen performed its obligations under terms of that contract or in the alternative, to the extent that it failed to do so, its non-performance was excused because of RCT's material breach of the contract as alleged herein.

40. Pursuant to the parties' contract, RCT had an obligation to use reasonable efforts to obtain enforceable patent protection for the licensed invention.

41. Notwithstanding this agreement, RCT and Dr. Srivastava intentionally and unreasonably violated their duty of candor before the PTO and engaged in the acts of inequitable conduct as described above, thereby destroying patent protection for the invention claimed in the '834 patent by rendering that patent's claims unenforceable.

42. This conduct was a material breach of the parties' contract, which directly damaged Avigen, and caused loss and detriment to Avigen in an amount that shall be proven at trial.

Second Claim for Relief

(Breach of the Implied Covenant of Good Faith and Fair Dealing)

43. Avigen incorporates the allegations and averments in paragraphs 1 through 36 as fully set forth in this claim for relief.

44. The parties' contract imposed upon each party an implied duty of good faith and fair dealing in its performance and enforcement.

45. RCT materially breached this implied covenant of good faith and fair dealing by engaging in the conduct as described herein, which rendered the valuable patent rights for which Avigen had bargained to be unenforceable.

46. RCT's breach directly damaged Avigen, and caused loss and detriment to it in an amount that shall be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Avigen prays that this Court enter judgment as follows:

1. For a determination that RCT and Dr. Srivastava violated their duty of candor before the PTO and committed inequitable conduct during the prosecution of the '834 patent, thereby rendering that patent's claims unenforceable;

2. For a determination that this conduct has materially breached the parties' contract;

3. For a determination that this conduct has materially breached the implied covenant of good faith and fair dealing;

4. For the rescission of the contract, thereby terminating all future obligations under the License Agreement and requiring the restoration of the consideration obtained from Avigen including all royalties paid and the return of all stock transferred pursuant to the License Agreement;

5. For, in the alternative to rescission, the recovery of all damages incurred by Avigen due to RCT's breach;

6. For costs of suit, attorneys fees, and interest, as provided for by statute or otherwise; and

7. For other and further relief as may be just and proper.

February 26, 2002

COOLEY GODWARD LLP

By: William G. Gaede III

Attorneys for Plaintiff
AVIGEN, INC.

JURY DEMAND

Plaintiff requests a jury trial on all issues triable thereby.

February 26 2002

COOLEY GODWARD LLP

By: William G. Gaede III

Attorneys for Plaintiff
AVIGEN, INC.